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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,368

04/20/2006

Frederick R. Kettinger

525.1089-PCT-US

5602

20311 7590 03/17/2008

LUCAS & MERCANTI, LLP  
475 PARK AVENUE SOUTH  
15TH FLOOR  
NEW YORK, NY 10016

EXAMINER

VO, TUYEN KIM

ART UNIT

PAPER NUMBER

2887

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,368	<b>Applicant(s)</b> KETTINGER ET AL.	
	<b>Examiner</b> Tuyen Kim Vo	<b>Art Unit</b> 2887	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02/19/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Acknowledgment**

1. This Office Action is responsive to the Amendment filed on 02/19/2008. The finality of the Office Action mailed 12/20/2007 is now withdrawn and the prosecution of the instant application is now reopened.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 contains the trademark/trade name Opacode. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe Opacode ink and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8, 11-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus et al. (US 6,543,692 B1, hereinafter "Nellhaus") in view of Sullivan et al. (US 5,992,742, hereinafter "Sullivan").

Re claims 1, 14 and 17, Nellhaus, as shown in figure 10, teaches a solid form drug (72) comprising a core portion (75) having sufficiently low friability to receive a printed or etched marking on a surface thereof; a readable printed or etched marking (data matrix 82) on the surface of the core, the marking providing identification/authentication of the oral dosage form. See column 4, lines 26-50.

However, Nellhaus fails to disclose or suggest the readable printed or etched marking is a covert readable printed or etched marking.

Sullivan teaches a marking code on the pill which is invisible. See column 8, lines 55-67 and column 12, lines 38-62.

In view of Sullivan's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the readable printed (data matrix 82) of Nellhaus with an invisible code (covert readable printed) as taught by

Sullivan so that the data cannot be seen or read by a human. Such modification would also help counter unauthorized or unintentional exchanges of pills in a container. See Sullivan: column 8, lines 55-67.

Re claims 2 and 19, the teachings of Nellhaus as modified by Sullivan have been discussed above. In addition, Sullivan further teaches a barcode is printed on a label of a pill, which has a code-receiving layer (a core portion) that has a film (a protein based film) coated prior to the printed being applied thereto. See column 11, line 36 to column 12, line 43.

Re claim 3, Nellhaus further teaches the printed or etched marking is a barcode (data matrix 82). See column 4, lines 51-54.

Re claim 4, Nellhaus further teaches the barcode is a 2D data matrix barcode. See column 1, lines 13-18.

Re claim 5, Sullivan further teaches the film coat contains a colorant (the gelatin film has slightly yellow color, see Webster's II, new college dictionary, Houghton Mifflin Company, Boston, New York, Copyright © 1995, page 464). See column 11, lines 36-38.

Re claim 6, Nellhaus further teaches the marking is readable with a barcode scanner (a pen, figure 13). See column 5, line 66 to column 6, line 2.

Re claim 7, Nellhaus further teaches the marking is readable with detection equipment which does not depend upon visible light waves. See column 2, lines 29-35 and column 3, lines 15-19.

Re claims 8 and 20, Nellhaus further teaches a covert marking thereon (hybrid data matrix symbol 90, figure 12). See column 5, lines 49-57.

Re claims 11 and 18, Nellhaus further teaches the surface of the core further comprises a debossed region (icon 75, figure 10, which serves as a debossed region) into which the printed or etched marking is place. See column 4, lines 44-47.

Re claim 12, Nellhaus further teaches the debossed region has a substantially horizontal plane with respect to the center of the core. See figure 10; column 4, line 44-47.

Re claims 13, 15, 16 and 21, Nellhaus further teaches the core has an ink coating applied to a portion thereof to the marking being applied thereto. See column 3, lines 10-22.

Re claims 23 and 24, the teachings of Nellhaus as modified by Sullivan have been discussed above. Nellhaus also teaches the different sizes (concentrating) of the marking such as 4x4, 5x5,..etc.., see column 1, lines 25-62. Therefore, to provide the marking with the range of about 2 to about 5 ppm is obvious from the different sizes of Nellhaus since it is just a variation of sizing.

In addition, Sullivan teaches a film (a protein based film such as keratin or gelatin film) coating on the code-receiving layer. See column 11, line 36 to column 12, line 43.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus to employ the film coated on the core portion (code-receiving layer) as taught by Sullivan with the amount as suggested

by Nellhaus so that to easily adhere to the pill which marking can be easily applied thereon. See column 11, lines 36-55 of Sullivan.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan as applied to claim 1 above, and further in view of Siegel (US 2004/0166063 A1).

Re claim 9, the teachings of Nellhaus as modified by Sullivan have been discussed above. However, Nellhaus as modified by Sullivan fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable by aroma.

Siegel teaches marking the pharmaceutical product (pills) with a covert scent profile which is detectable by aroma. See [0102] and [0103].

In view of Siegel's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Sullivan by providing the marking which is detectable by scent as taught by Siegel to the cover marking of Nellhaus as modified by Sullivan in order to prevent counterfeiting of the aromas and to identify the pharmaceutical formulation/products.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan as applied to claims 1/8 above, and further in view of Johnson et al. (US 6,171,618 B1, hereinafter "Johnson").

Re claim 10, the teachings of Nellhaus as modified by Sullivan have been discussed above. However, Nellhaus as modified by Sullivan fails to teach the covert marking (hybrid data matrix symbol 90, figure 12) is detectable using HPLC.

Johnson teaches a HPLC system uses to monitor or detect the dosage. See column 14, lines 3-29.

In view of Johnson's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the covert marking of Nellhaus as modified by Sullivan so that it can be detected by HPLC as taught by Johnson since HPLC is used to monitor or detect the chemical using UV detecting.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nellhaus as modified by Sullivan as applied to claims 14/15 above, and further in view of Cruttenden et al. (US 2003/0056667 A1, hereinafter "Cruttenden").

Re claim 22, the teachings of Nellhaus as modified by Sullivan have been discussed above. However, Nellhaus as modified by Sullivan fails to teach the pad printing is applied using an Opacode ink.

Cruttenden teaches printing the pharmaceutical product using an Opacode ink. See [0011].

In view of Cruttenden's teachings, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the invention of Nellhaus as modified by Sullivan by using the opacode ink as taught by Cruttenden



since Opacode ink is FD&C approved and it may be easily and rapidly printed without runs, smearing or blotting on the product.

### ***Response to Arguments***

8. Applicant's arguments with respect to Nellhaus fails to teach "the marking being a covert marking" in light of claims 1-24 have been considered but are moot in view of the new ground(s) of rejection. The limitation has now been treated on the merit as seen above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuyen Kim Vo whose telephone number is (571)270-1657. The examiner can normally be reached on Monday - Friday, 7:30a.m. - 5:00p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven S. Paik can be reached on (571) 272-2404. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tuyen Kim Vo  
Examiner  
Art Unit 2887  
March 3, 2008.

/STEVEN S. PAIK/  
Supervisory Patent Examiner, Art  
Unit 2887

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